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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/646,383
Filing Date: August 21, 2003
Appellant(s): COPA ET AL.

Daniel C. Schulte
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/22/2010 appealing from the Office action mailed 05/24/2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

11/804,114 and 10/919,775

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claims 1-9, 11-14, and 26-44

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,540,701	SHARKEY ET AL.	7-1996
6,461,367	KIRSCH ET AL.	10-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by **Sharkey et al.** (U.S. Patent No. **5,540,701**).

Sharkey et al. disclose an anastomosis device comprising a hollow, elongate flexible catheter body **18** having a proximal end and a distal end, the distal end comprising a catheter body wall, an inflatable balloon **32** at the distal end, a drainage aperture **28** at the distal end and a drainage means **22** connected to the drainage aperture for draining urine from a bladder extending to a port at the proximal end, and a tissue approximating structure or inflatable balloon **36** that can be extended (inflated) and retracted (deflated), from the catheter body wall along the distal end of the catheter body on a proximal side of the inflatable balloon for holding severed tissue in contact for healing, wherein the inflatable balloon is on a proximal side of the drainage aperture (Figures 9, 11, 13). The device may be installed in a body having a prostate removed, with the catheter inside of the urethra and the balloon in the bladder, the tissue approximating structure being capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue, and combinations of these (col. 6, lines 51-65). An actuating (inflation) means is connected to the tissue approximating means and extends from the tissue approximating means to the proximal end.

In regards to claims 26-29, the first tissue approximating structure may be considered to be the first inflatable balloon **32** and the second tissue approximating structure may be considered to be the second inflatable balloon **36**, both which are

located on a proximal side of the drainage aperture **28**, wherein each of the first and second tissue approximating structures can be extended and retracted (inflated and deflated) from the catheter body wall.

The balloon or the first tissue approximating structure **32** and the second tissue approximating structure **36** may both be extended and retracted at a fixed location along the distal end of the catheter body with respect to the distal and proximal ends of the catheter body.

The tissue approximating structures or balloons may be elongate structures since the geometry of the balloons may "impart various geometrical configurations that are then used to expand proximal and distal ends **12** and **14**" which may be conical (col. 7, lines 23-41), or "a generally cylindrical shape" (col. 5, lines 50-59).

Claims 3-8, 13, 30-34, 36-38, 40-42, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sharkey et al.** (U.S. Patent No. **5,540,701**) in view of **Kirsch et al.** (U.S. Patent No. **6,461,367**).

Sharkey et al. disclose the claimed device except for the tissue approximating structure or the second tissue approximating structure comprising of multiple distal tines and multiple proximal tines that all extend and retract from the catheter body wall at fixed locations along the distal end of the catheter body, the fixed locations being fixed with respect to the distal and proximal ends of the catheter body.

In Figures 1-9 Kirsch et al. teach multiple distal tissue approximating tines ('prongs') **30** (on **24**) and opposing multiple proximal tissue approximating tines (on **16**;

see col. 3, lines 48-55) that all extend and retract from a catheter body wall at fixed locations along the distal end of the catheter body, the fixed locations being fixed with respect to the distal and proximal ends of the catheter body. For instance, when the distal end **24** of the catheter body and the proximal end **16** of the catheter body are fixed or connected together, the distal tines may be extended and retracted by actuating knob **28** at a fixed location through apertures **46**, and similarly the proximal tines may be extended and retracted by actuating knob **18** through apertures at a fixed location to secure a clip/anastomosis device **38** (Figures 1 and 5; see col. 3, line 32 to col. 4, line 14). Opposing tines **30** may also be used as shown in Figures 11A-B.

It would have been obvious to one of ordinary skill in the art at the time of invention to replace the (second) tissue approximating structure of Sharkey et al. with one that comprises multiple distal and proximal opposing tines at the distal end of a catheter body, as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines to ensure proper connection between the urethra and bladder (col. 1, lines 38-40, Kirsch et al.), as well as to selectively approximate tissue when desired.

Sharkey et al. also acknowledge that instead of the inflatable balloon tissue approximating structures **32** and **36** that "distensible members that are mechanically extended and retracted in order to deploy the proximal and distal ends **12** and **14** of [the anastomosis device]" may be used (col. 7, lines 15-22), and therefore it would have been obvious to one of ordinary skill in the art to consider the teaching of distal and

proximal selectively retractable tines of Kirsch et al. for deploying the anastomosis device in Sharkey et al.

(10) Response to Argument

1. Appellant generally argues that the balloons **32**, **36** of Sharkey et al. (Figures 11 and 13) may not be considered as "elongate tissue approximating structures" as necessitated by the claims, since the present application (paragraph 30) discusses two different types of tissue approximating structures: "one or multiple balloon or balloon-like structures" and alternately "elongate structures such as a needle, tine, prod, probe," and therefore an elongate structure must exclude a balloon structure in view of the present specification. The examiner disagrees. As mentioned above, the tissue approximating structures or balloons may be considered as elongate structures since the geometry of the balloons may "impart various geometrical configurations that are then used to expand proximal and distal ends **12** and **14**" which may be conical (col. 7, lines 23-41), or "a generally cylindrical shape" (col. 5, lines 50-59) and therefore may be considered elongate structures. Furthermore, the balloons **32**, **36** of Sharkey et al. read on an "elongate tissue approximating structure" since they exhibit a length when deflated or inflated, or are drawn out to a greater length when inflated.
2. Next, appellant argues that one of ordinary skill in the art would not have modified Sharkey et al. with Kirsch et al., since removing the balloon **36** from the Sharkey et al. device and replacing it with the elongate tissue approximating structures ("prongs") **30** of Kirsch et al. (Figures 1-9) would remove the utility required of the

Sharkey et al. device since the expanding surface area structure of a balloon is required to expand the helical ends of anastomosis device **12/14** rather than expandable tine structures of Kirsch et al. and therefore the modified device of Sharkey et al. with Kirsch et al. would be rendered inoperable. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As maintained above, Kirsch et al. teach using elongate tissue approximating structures **30** that selectively expand and retract to secure a clip/anastomosis device **38** and facilitating the approximation of tissue portions by anchoring the urethral stump and bladder neck to ensure proper connection between the urethra and bladder (col. 1, lines 38-40), and therefore it would have been obvious to one of ordinary skill in the art to modify the balloons **32** and **36** of Sharkey et al. with the structures **30** of Kirsch et al to selectively expand/retract the tissue approximating members. Furthermore, since Sharkey et al. also acknowledge that "distensible members that are mechanically extended and retracted in order to deploy the proximal and distal ends **12** and **14** of [the anastomosis device]" may be used (col. 7, lines 15-22) instead of the inflatable balloon tissue approximating structures **32** and **36**, one of ordinary skill in the art would look to the Kirsch et al. teaching of distal and proximal selectively retractable elongate tissue approximating structures **30** for deploying the anastomosis device **12/14** in Sharkey et al.

3. Lastly, appellant argues that the elongate tissue approximating structures **30** of Kirsch et al. do not anchor or secure tissue, but rather engage tissue. The examiner does not rely on the Kirsch et al. reference to teach an elongate tissue approximating structure that anchors or secures tissue, but rather relies on the Kirsch et al. teaching of selectively expandable/retractable elongate tissue approximating structure **30** that are capable of contacting tissue or holding severed tissue in contact for healing, as required by the claims. It is noted that the features upon which applicant relies (i.e., "anchoring" and "securing") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Diane Yabut/
Examiner, Art Unit 3734

Art Unit: 3734

Conferees:

Gary Jackson

/Gary Jackson/
Supervisory Patent Examiner, Art Unit 3734
March 12, 2011

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